UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,497	10/30/2003	Stephen C. Suffin	CNSR-07141	8061

23535 7590 08/07/2008

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,497	SUFFIN ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 7, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *4-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed November 7, 2007 have been received and entered into the application.

The finality of record indicated in the Office Action August 16, 2007 is an inadvertent error on the form PTOL-326 (Office Action Summary), the status of the Application was errously marked final due to a typographical error. It should have been checked for the "non-final" status.

Office Action Summary	Application No.	Applicant(s)	
	10/697,497	SUFFIN ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on July 26, 2007.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Action Summary

The rejection of claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Quessy et al. (US 2002/0147196 A1) further in view of Zakrzewska et al. (#84, PTO-1449), (Journal of Neurology, Neurosurgery, and Psychiatry 1989) is being **maintained** for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed November 7, 2007 have been fully considered but they are not persuasive. Applicants argue that the rEEG data is relevant to neuropathy because that neuroaphty is disclosed in the specification as a neurological disorders. This is not found persuasive because rEEG data is to measure the response pattern related to characterize features of brain function underlying a broad range of psychiatric symptoms. The employment of rEEG data is not a proper indicator to show the effect of neuropathic pain because neuropathic pain involves peripheral nervous system rather than central. It is Applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpect and signficiant relative to the treatment of neuropathic pain. See MPEP 716.02 (d). Applicants argue that the intended use is not a relevant factor becuse the instant claims are drawn to the composition not method of treatment claims. This is not persuasive becuase the intended use of the each of the compound useful for the same utility (treatment of neuropathic pain) provides motivation of interchange one compound for the another when specific compound are taught as having the same analgesic activity and the

efficacy in the treatment of the neuropathic pain. It is noted that Quessy et al. lists oxcarbazepine along with lamotrigine as useful for the treatment of neuropathic pain. Therefore, it would have been obvious to one of ordinary skill in the art to interchange one compound for the another when specific compounds are taught as having the same analgesic activity and the efficacy of treating neuropathic pain is retained. Applicants argue that The second Suffin Declaration provides sufficient evidence to show that oxcarbazepine and lamotrigine does not work as expected by one having ordinary skill in the art because these two drugs have opposite results. The second Suffin Declaration has been carefully review and considered. However, it is not persuasive because the data showing that oxcarbazepine has an overall rEEG response pattern that is consistent with stimulant drugs which is contrary to lamotrigine having an overall rEEG response pattern that is consistent with depressant drugs do not relate to the treatment of neuropathic pain involving peripheral nervous system. Therefore, it is irrelevant to measure the effect in neuropathic pain. In this case, it would have been obvious to one of ordinary skill in the art to modify the composition of Quessy et al. by replacing lamotrigine with oxcarbazepine because Quessy et al. teach that bupropion can be formulated with any one of disclosed sodium channel blockers including oxcarbazepine or lamotrigine and because Quessy et al. teach that oxcarbazepine and lamotrigine are equivalents as both having the **analgesic properties** for the **treatment of neuropathic pain** in combination with bupropion. The motivation to combine need not be Applicant's motivation to invent. In re Dillon 16 USPQ 2d 1897, (Fed. Cir. 1990). One of ordinary skill in the art would be motivated to make such a modification with

oxcarbazepine in order to fulfill the need of a pharmaceutical composition and providing variety for the treatment of neuropathic pain, not only possessing anti-neuralgic properties but also lacking side-effects. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of August 16, 2007 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quessy et al. (US 2002/0147196 A1) of record further in view of Zakrzewska et al. (#84, PTO-1449), (Journal of Neurology, Neurosurgery, and Psychiatry 1989) of record.

Quessy et al. teach a pharmaceutical composition comprising **bupropion** and sodium channel blockers including **oxcarbazepine and lamotrigine** useful for the treatment of **neuropathic pain**. (page 5, claims 1-3). Quessy et al. illustrate the composition comprising **bupropion and lamotrigine** (page 5, Example 3, claim 6). Quessy et al. teach that using the test compound lamotrigine in a pre-clinical

experiment, no adverse side effects were observed. ([0038]). Quessy et al. also teach that the composition can be formulated with **mixtures of NE-reuptake inhibitors which exert analgesic activity (analgesics)**. (page 1, [0009], [0010]). Quessy et al. further teach that the composition can be formulated as a **transdermal patch**, **sterile injectable solution**, **tablet**, **capsules**, **oral liquid** or **a sterile liquid for injection** and can be formulated with suitable **polymeric** materials. ([0021]-[0027]). Quessy et al. additionally teach that the composition manifests **synergism** in the treatment of neuropathic pain ([0009]). Quessy et al. lastly teach that there is a need for a pharmaceutical composition that can alleviate neuropathic pain or/its symptoms effectively. (page 1, [0004], [0007]).

However, Quessy et al.'s illustrated composition (example 3) uses lamotrigine with bupropion, rather than oxcarbazepine as instantly claimed.

Zakrzewska et al. teach that **oxcarbazepine** possesses **antineuralgic properties,** is effective in the management of intractable **trigeminal neuralgia,** and elicits an **excellent** therapeutic response in **controlling pain without side effects**. (abstract).

It would have been obvious to one of ordinary skill in the art to modify the composition of Quessy et al. by replacing lamotrigine with oxcarbazepine, because Quessy et al. teach that bupropion can be formulated with any one of disclosed sodium channel blockers including oxcarbazepine or lamotrigine, and because Quessy et al. teach that oxcarbazepine and lamotrigine are equivalents both having the anti-neuralgic properties for treating neuropathic pain in combination with bupropion. Further,

Zakrzewska et al. also teach that oxcarbazepine has no side effects. One of ordinary skill in the art would be motivated to make such a modification with oxcarbazepine in order to fulfill the need of a pharmaceutical composition and providing variety for the treatment of neuropathic pain, not only possessing anti-neuralgic properties but also lacking side-effects as taught by Zakrzewska et al. There is a reasonable expectation of successfully treating neuropathic pain without side effects with a combination of bupropion and oxcarbazepine, the latter well taught by Zakrzewska et al. as possessing excellent anti-neuralgic properties with an excellent therapeutic response in controlling pain. With regard to further combining with a third drug as set forth in claim 2 and the specified formulation as set forth in claim 3, all deemed obvious because Quessy et al. teach that NE-reuptake inhibitors exert analgesic activity (analgesics) and, therefore, can be incorporated in the obvious combination and because the various formulations set forth in claim 3 are taught by Quessy et al. as suitable formulations for the obvious combination. One would have been motivated to further incorporate analgesics in a mixture to the combination in various formulations disclosed by Quessy et al. in order to successfully formulate an ultimate regimen for the treatment of neuropathic pain possessing at least one synergistic effect disclosed by Quessy et al. without a side effect. Absent any evidence to contrary, there would have been a reasonable expectation of successfully improving the anti-neuropathic pain composition of Quessy et al. by combining bupropion and oxcarbazepine in order to fulfill the need of a pharmaceutical composition that can alleviate neuropathic pain without as a side effect.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
August 5, 2008